



## General

### Guideline Title

Validating whole slide imaging for diagnostic purposes in pathology. Guideline from the College of American Pathologists Pathology and Laboratory Quality Center.

### Bibliographic Source(s)

Pantanowitz L, Sinard JH, Henricks WH, Fatheree LA, Carter AB, Contis L, Beckwith BA, Evans AJ, Otis CN, Lal A, Parwani AV. Validating whole slide imaging for diagnostic purposes in pathology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. Arch Pathol Lab Med. 2013 Dec;137(12):1710-22. [55 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

The Grades of Recommendation (A-D) and Description of Guidance (Recommendation, Suggestion, Expert Consensus Opinion, No Recommendation Offered) are defined at the end of the "Major Recommendations" field.

1. All pathology laboratories implementing whole slide imaging (WSI) technology for clinical diagnostic purposes should carry out their own validation studies. (Expert consensus opinion)
2. Validation should be appropriate for and applicable to the intended clinical use and clinical setting of the application in which WSI will be employed. Validation of WSI systems should involve specimen preparation types relevant to the intended use (e.g., formalin-fixed paraffin-embedded tissue, frozen tissue, immunohistochemical stains, cytology slides, hematology blood smears). *Note: If a new intended use for WSI is contemplated, and this new use differs materially from the previously validated use, a separate validation for the new use should be performed.* (Recommendation Grade A)
3. The validation study should closely emulate the real-world clinical environment in which the technology will be used. (Recommendation Grade A)
4. The validation study should encompass the entire WSI system *Note: It is not necessary to validate separately each individual component (e.g., computer hardware, monitor, network, scanner) of the system nor the individual steps of the digital imaging process.* (Recommendation Grade B)
5. Revalidation is required whenever a significant change is made to any component of the WSI system. (Expert consensus opinion)
6. A pathologist(s) adequately trained to use the WSI system must be involved in the validation process. (Recommendation Grade B)
7. The validation process should include a sample set of at least 60 cases for one application (e.g., hematoxylin-eosin [H&E]-stained sections)

of fixed tissue, frozen sections, cytology, hematology) that reflects the spectrum and complexity of specimen types and diagnoses likely to be encountered during routine practice. *Note: The validation process should include another 20 cases for each additional application (e.g., immunohistochemistry, special stains).* (Recommendation Grade A)

8. The validation study should establish diagnostic concordance between digital and glass slides for the same observer (i.e., intraobserver variability). (Suggestion Grade A)
9. Digital and glass slides can be evaluated in random or nonrandom order (as to which is examined first and second) during the validation process. (Recommendation Grade A)
10. A washout period of at least 2 weeks should occur between viewing digital and glass slides. (Recommendation Grade B)
11. The validation process should confirm that all of the material present on a glass slide to be scanned is included in the digital image. (Expert consensus opinion)
12. Documentation should be maintained recording the method, measurements, and final approval of validation for the WSI system to be used in the clinical laboratory. (Expert consensus opinion)

#### Definitions:

#### Body of Evidence Matrix Component

	A Excellent	B Good	C Satisfactory	D Poor
Evidence Base	Several level I or level II studies with low risk of bias	One or two level II studies with low risk of bias or a systematic review/multiple level III studies with low risk of bias	Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	Level IV studies, or level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical Impact	Very large	Substantial	Moderate	Slight or restricted
Generalizability	Population/s studied in body of evidence are the same as the target population for the guideline	Population/s studied in the body of evidence are similar to the target population for the guideline	Population/s studied in body of evidence differ from target population for guideline but it is clinically sensible to apply this evidence to target population	Population/s studied in body of evidence differ from target population and hard to judge whether it is sensible to generalize to target population
Applicability	Directly applicable to United States (US) and international healthcare context	Applicable to US and international healthcare context with few caveats	Probably applicable to US and international healthcare context with some caveats	Not applicable to US or international healthcare context

The overall grade of each recommendation was obtained by rating all components of the evidence (see the "Rating Scheme for the Strength of the Evidence" field). The overall grade indicates the strength of the body of evidence to assist the users of clinical practice guidelines in making appropriate and informed clinical judgments. Grade A or B evidence supports *recommendations*, the term used for guidance based on a body of evidence that can be trusted to guide clinical practice in all or most situations. Grade C evidence is insufficient to support a recommendation; instead the term *suggestion* is used, for which care should be taken in application. Suggestions may also reflect guidance in cases where the evidence is conflicting or inconclusive. Grade D evidence is weak and does not provide support for either recommendations or suggestions. However, the guideline authors may choose to provide guidance in the form of an *expert consensus opinion* where they believe that guidance will result in improved patient care, even in cases where the evidence is low or lacking. In this guideline, guidance includes recommendations, suggestions and expert consensus opinion; there were no instances of *no recommendation offered*.

#### Overall Grade of Recommendation

Grade of Recommendation	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

#### Description of Guidance\*

Recommendation	For moderate and highest level of evidence (Grade A/B) or where statements are unlikely to change based on further evidence. Note: Can also be in the negative, i.e., <i>Recommend Against</i> or <i>Not Recommended</i> .
Suggestion	For inconclusive, conflicting and/or weak evidence (Grade C) or where statements most likely correct but could be better supported by additional data.
Expert Consensus Opinion	There is a gap, poor evidence (Grade D) or no evidence to support statement but necessary to address the topic. May be qualified with "requires future studies to be conducted."
No Recommendation Offered	No statement generated for this key question/topic.

\*Developed by the College of American Pathologists (CAP) Pathology and Laboratory Quality Center.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Any disease or condition requiring pathological review of histologic sections, cytology slides, and/or hematology slides to render diagnosis

### Guideline Category

Diagnosis

Technology Assessment

### Clinical Specialty

Pathology

### Intended Users

Allied Health Personnel

Clinical Laboratory Personnel

Health Care Providers

Physicians

## Guideline Objective(s)

To recommend validation requirements for whole slide imaging (WSI) systems to be used for diagnostic purposes

## Target Population

Patients with any disease or condition requiring pathological review of histologic sections, cytology slides, and/or hematology slides to render diagnosis

## Interventions and Practices Considered

Validation of whole slide imaging (WSI) processes

## Major Outcomes Considered

Correlation between whole slide imaging (WSI) (digitized slides) and glass slides, particularly with respect to accuracy, concordance, average diagnostic certainty, and sensitivity and specificity in the context of validation requirements

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The charge to the panel was "to recommend validation requirements for whole imaging systems (WSI) used for diagnostic purposes." The central question that the panel addressed was "What should be done to validate a whole slide digital imaging system for diagnostic purposes before it is placed in clinical service?"

A computerized search was conducted during the period from September 28, 2010 to January 23, 2012 in the electronic databases: OVID MEDLINE, CSA Illumina Conference Papers Index and Google Scholar for articles from January 2000 through January 2012. The search used the following terms:

- Whole slide imaging OR Virtual or Digital microscopy OR Digital pathology OR Teleconsultation OR Telemicroscopy – AND
- Validation

Alternate terms *digitized slide* and *whole slide scanner* were also used. Reference lists from identified articles were scrutinized for articles not identified in the above search.

### Eligible Study Designs

The search included all types of study design. In addition to articles, the search identified published abstracts presented at various conferences, including international meetings. The initial search was not limited to the English language, and one Russian article was included for the full text

review.

#### Inclusion Criteria

Published studies were selected for full text review if they met the following criteria:

1. The study referred to WSI.
2. The study pertained to clinical use or investigative research.

All clinical fields (e.g., pathology, veterinary) were allowed.

#### Exclusion Criteria

Publications involving static and robotic digital imaging, purely technical components, only educational applications, and image analysis were excluded.

#### Environmental Scan

In the United States, the Food and Drug Administration (FDA) convened a Hematology and Pathology Devices Panel hearing in October 2009 that focused on how best to regulate WSI systems that are to be used for primary diagnosis in surgical pathology. After the October 2011 Pathology Visions Meeting, CAP Today published an article summarizing the FDA stance at that time.

## Number of Source Documents

Twenty seven studies received a strong enough score to be considered for data extraction and review by the contracted methodologist. After data extraction verification by College of American Pathologists staff, 23 studies were included in the final evidence.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

#### Level of Evidence

- Level I: Evidence from systematic reviews of appropriate level II studies
- Level II: Evidence from good quality diagnostic studies or randomized controlled trials
- Level III: Evidence from low quality comparative diagnostic studies
- Level IV: Evidence from diagnostic studies without a reference standard

#### Body of Evidence Matrix Component

	A Excellent	B Good	C Satisfactory	D Poor
Evidence Base	Several level I or level II studies with low risk of bias	One or two level II studies with low risk of bias or a systematic review/multiple level III studies with low risk of bias	Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	Level IV studies, or level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical Impact	Very large	Substantial	Moderate	Slight or restricted

Generalizability	Population/s studied in body of evidence are the same as the target population for the guideline	Population/s studied in the body of evidence are similar to the target population for the guideline	Population/s studied in body of evidence differ from target population for guideline but it is clinically sensible to apply this evidence to target population	Population/s studied in body of evidence differ from target population and hard to judge whether it is sensible to generalize to target population
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## Methods Used to Analyze the Evidence

### Systematic Review

## Description of the Methods Used to Analyze the Evidence

### Quality Assessment and Grading of the Included Evidence

The literature review was performed in duplicate by 2 members of the expert panel. A third reviewer was involved if the 2 were not able to reach consensus. A contracted methodologist and College of American Pathologists (CAP) staff performed final data extraction. Each study was assessed for strength of evidence, which consisted of level of evidence, quantity, size of the effect, statistical precision, and quality (risk of bias). The quality assessment of the studies was performed by using the Whiting et al. (2003) instrument.\* The other components of evidence, such as consistency, clinical impact, generalizability, and applicability, to digital pathology were also considered when determining the strength of evidence. The overall grade for a recommendation was obtained by considering the component scores of individual items.

For *strength* of the evidence, the authors considered the level of evidence, its quantity, size of the overall effect, statistical precision, and quality of included studies. The *level* of evidence was based on the study design as follows: Level I was evidence from systematic reviews of appropriate level II studies; level II was evidence from good quality diagnostic studies or randomized controlled trials; level III was evidence from low quality comparative diagnostic studies; level IV was evidence from diagnostic studies without a reference standard. Level I and II evidence was considered most appropriate to answer the clinical question put to this panel. The *quantity* of evidence refers to the number of studies and number of patients/cases included for each outcome in the recommendation. The *size of the effect* refers to the overall effect and its statistical precision. It was measured as weighted mean difference or risk ratio and confidence intervals. The *quality of studies* reflected how well the studies were designed to eliminate bias, including how the subjects, cases or tests were selected, allocated to groups (study or test and control or standard), managed, followed up, and analyzed. The methodological quality of diagnostic study was critically appraised using Whiting et al. (2003) checklist.\* All these components of the evidence base were considered while allocating an overall score to strength of evidence.

For consistency, the authors assessed both the clinical and statistical heterogeneity among the studies. The clinical heterogeneity was the variability regarding patients, disease state, and type of test to diagnose a condition and its comparator, and outcome measured. In the presence of marked clinical heterogeneity the studies were not meta-analyzed nor subgroup meta-analysis was performed. The statistical heterogeneity was assessed by performing a meta-analysis and was measured as  $I^2$  and P value.

For clinical impact, the authors assessed the potential benefits of test or intervention to the population and the relevance of evidence to the clinical question of the recommendation. In addition, the authors also considered the size of the effect, its statistical precision, and the relevance of effect of a test or intervention to the patients compared with other management options if available. The clinical impact could vary from very large to slight clinical impact.

For generalizability, the authors observed how well the subjects and settings of the included studies matched those of the recommendation. Population parameters such as gender, age, ethnicity, and baseline risk, and the level of care were considered. If the population studied in the body of evidence was the same as the target population for the guideline, it was scored as excellent. On the other hand, if these populations were substantially different it was scored poor.

For applicability, the authors considered how well the entire evidence favoring the recommendations was relevant to the United States and international populations. Evidence which was directly applicable to the United States and international healthcare scored as excellent, whereas that

which was not scored as poor.

\*Whiting P, Rutjes A, Reitsma J, Bossuyt P, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. *BMC Med Res Methodol.* 2003;3:25.

## Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

## Description of Methods Used to Formulate the Recommendations

### Panel Composition

The College of American Pathologists (CAP) Pathology and Laboratory Quality Center convened an expert panel consisting of members with expertise and experience in digital pathology relevant to using whole slide imaging (WSI) for clinical purposes. Members included practicing US and Canadian pathologists and CAP staff. The CAP approved the appointment of the project, chair, and expert panel members.

### CAP Expert Panel Literature Review and Analysis

Initially, the chair sent a Zoomerang study with 58 potential WSI validation statements to all expert panel members and instructed them to respond with Agree, Disagree, or Don't Know and provide comment. Results included 7 statements with 100% agreement, 9 with 88% agreement, 16 with 75% agreement, 10 with 62% agreement, 8 with 50% agreement, 4 with 38% agreement, 3 with 25% agreement, and 1 statement with a 0% agreement. The expert panel proceeded to review all statements and discuss those with an agreement rate of 62% or less. During discussion, variable interpretation of the statement was found to be the largest cause of disagreement amongst members. Resolution was obtained by majority consensus and many statements were eliminated from recommendation consideration, considered duplicate statements or reduced to comments of interest to address in the manuscript.

The expert panel met in a face-to-face meeting September 2010; additional work was completed through 18 teleconference webinars, collaboration site access (Oracle WebCenter Spaces v11.1.1.2.0) and electronic mail. The purpose of the panel meeting was to refine the scope of the document and address the most discordant Zoomerang digital pathology validation statements amongst panel members.

An open comment period was held from July 22, 2011 through August 21, 2011. Thirteen statements (representing potential recommendations) with brief background information and an open ended question were posted online on the CAP Web site. An announcement was sent to the following societies deemed to have interest:

- College of American Pathologists (CAP)
- Association of Directors of Anatomic and Surgical Pathology (ADASP)
- American Society of Clinical Pathology (ASCP)
- Association for Pathology Informatics (API)
- Digital Pathology Association (DPA)
- International Academy of Digital Pathology (IADP)
- Association for Pathology Chairs (APC)
- Canadian Association of Pathologists (CAP-APC)
- Food and Drug Administration (FDA)

The website received 531 comments in total (Agree, Disagree, and Comment). Each expert panel member was assigned 1 to 2 statements for which to review all comments received and provide an overall summary to the rest of the panel. Following their review the panel members determined whether to maintain the original statement/recommendation as is, revise it with minor language change, or consider a major statement/recommendation change. Based upon the fact that most statements achieved over 80% agreement with the original recommendation, the expert panel elected to make minor modifications to the statements for clarification and/or explain any pertinent issues in further detail within the manuscript.

Only two statements did not achieve 80% agreement and the expert panel accordingly made major revisions of these recommendations. Seven statements were revised with only minor language changes and four statements were maintained with the original language. Additional revisions were made by the panel after the quality of evidence was assessed. Resolution of major and minor changes was obtained by majority consensus of the panel.



Seven hundred sixty-seven studies met the search term requirements. For title/abstract review, each study underwent an inclusion-exclusion, dual independent review conducted by staff, chair, and a third member referee when staff/chair review did not achieve unanimous agreement. The initial title/abstract review eliminated 655 studies. Dual independent expert panel members and staff reviewed the remaining 112 studies in full.

To include the study for grading by the methodologist, composite scoring by both reviewers had to be a score of four or above). The expert panel members unanimously eliminated 31 studies and the chair eliminated an additional 54 studies for total of 85 exclusions in full text review. Twenty seven studies received a strong enough score to be considered for data extraction and review by the contracted methodologist. After data extraction verification by CAP staff, 23 studies were included in the final evidence. Any excluded article was available as discussion or background references.

The expert panel performed preliminary data extraction in the following areas: year of publication, country of origin, publication type, application of study, subspecialty of study, number of pathologists (or individuals), numbers of cases, validation method, reported concordance and outcome measurement. All members of the expert panel participated in the draft manuscript.

## Rating Scheme for the Strength of the Recommendations

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No Recommendation Offered	No statement generated for this key question/topic.

\*Developed by the College of American Pathologists (CAP) Pathology and Laboratory Quality Center.



## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

An independent review panel (IRP) was assembled to review the guideline and recommend approval to the College of American Pathologists (CAP) Transformation Program Office Steering Committee, which had final approval authority. The IRP was masked to the expert panel and vetted through the conflict of interest process. Because of the nature of the content, input from industry was considered. The Executive Committee of the Digital Pathology Association was sent a confidential courtesy paper copy during the final review process.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

- Validation of whole slide imaging (WSI) systems will improve their clinical use in pathology by helping pathologists and laboratories determine their effectiveness, thereby reducing the potential risk of misdiagnosis due to artifacts or other unmitigated problems with this technology.
- Clinical validation should also serve to meet compliance with emerging regulations that pertain to WSI for clinical diagnostic use.

### Potential Harms

Not stated

## Qualifying Statements

### Qualifying Statements

The College of American Pathologists (CAP) developed the Pathology and Laboratory Quality Center as a forum to create and maintain evidence-based practice guidelines and consensus statements. Practice guidelines and consensus statements reflect the best available evidence and expert consensus supported in practice. They are intended to assist physicians and patients in clinical decision making and to identify questions and settings for further research. With the rapid flow of scientific information, new evidence may emerge between the time a practice guideline or consensus statement is developed and when it is published or read. Guidelines and statements are not continually updated and may not reflect the most recent evidence. Guidelines and statements address only the topics specifically identified therein and are not applicable to other interventions, diseases, or stages of diseases. Furthermore, guidelines and consensus statements cannot account for individual variation among patients and cannot be considered inclusive of all proper methods of care or exclusive of other treatments. It is the responsibility of the treating physician or

other health care provider, relying on independent experience and knowledge, to determine the best course of treatment for the patient. Accordingly, adherence to any practice guideline or consensus statement is voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances and preferences. The CAP makes no warranty, express or implied, regarding guidelines and statements and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The CAP assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this statement or for any errors or omissions.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Staying Healthy

### IOM Domain

Effectiveness

## Identifying Information and Availability

### Bibliographic Source(s)

Pantanowitz L, Sinard JH, Henricks WH, Fatheree LA, Carter AB, Contis L, Beckwith BA, Evans AJ, Otis CN, Lal A, Parwani AV. Validating whole slide imaging for diagnostic purposes in pathology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. Arch Pathol Lab Med. 2013 Dec;137(12):1710-22. [55 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2013 May 1

## Guideline Developer(s)

College of American Pathologists - Medical Specialty Society

## Source(s) of Funding

The College of American Pathologists (CAP) provided funding for the administration of the project; no industry funds were used in the development of the guideline. Panel members volunteered their time and were not compensated for their involvement.

## Guideline Committee

College of American Pathologists (CAP) Pathology and Laboratory Quality Center Expert Panel

## Composition of Group That Authored the Guideline

*Panel Members:* Liron Pantanowitz, MD, Department of Pathology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; John H. Sinard, MD, PhD, Department of Pathology, Yale University School of Medicine, New Haven, Connecticut; Walter H. Henricks, MD, Pathology and Laboratory Medicine Institute, Cleveland Clinic, Cleveland, Ohio; Lisa A. Fatheree, BS, SCT(ASCP), College of American Pathologists, Northfield, Illinois; Alexis B. Carter, MD, Department of Pathology and Laboratory Medicine, Emory University, Atlanta, Georgia; Lydia Contis, MD, Department of Pathology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; Bruce A. Beckwith, MD, Department of Pathology, North Shore Medical Center, Salem, Massachusetts; Andrew J. Evans, MD, PhD, Laboratory Medicine Program, University Health Network, Toronto, Ontario, Canada; Christopher N. Otis, MD, Department of Pathology, Baystate Medical Center, Tufts University School of Medicine, Springfield, Massachusetts; Avtar Lal MD PhD, University Hospital, London Health Science Center, London, Ontario, Canada; Anil V. Parwani, MD, PhD, Department of Pathology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

## Financial Disclosures/Conflicts of Interest

Prior to acceptance on the expert panel, potential members completed the College of American Pathologists (CAP) conflict of interest disclosure process, whose policy and form requires disclosure of material financial interest in, or potential for benefit of significant value from, the guideline's development or its recommendations (see Appendix of the original guideline document). The potential members completed the conflict of interest disclosure form, listing any relationship that could be interpreted as constituting an actual, potential, or apparent conflict. Two potential members were not appointed based on this policy.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the [Archives of Pathology & Laboratory Medicine Journal Web site](#) .

## Availability of Companion Documents

The following are available:

- Pantanowitz L, Sinard JH, Henricks WH, Fatheree LA, Carter AB, Contis L, Beckwith BA, Evans AJ, Otis CN, Lal A, Parwani AV.

Validating whole slide imaging for diagnostic purposes in pathology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. Supplemental digital content. Arch Pathol Lab Med. 2013 May 1. Electronic copies: Available from the [Archives of Pathology & Laboratory Medicine Journal Web site](#) .

- Validating whole slide imaging (WSI) for diagnostic purposes in pathology guideline. Summary of recommendations. 2013. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the [College of American Pathologists \(CAP\) Web site](#) .
- CAP digital pathology guideline overview and discussion. Webcast. 2013 May 17. Available from the [CAP Web site](#) .
- Validating whole slide imaging systems for diagnostic purposes in pathology. Slide presentation. 2013 May 1. 41 p. Electronic copies: Available in PDF from the [CAP Web site](#) .
- CAP validating whole slide imaging (WSI) for diagnostic purposes in pathology. Frequently asked questions. 2013 May 1. 6 p. Electronic copies: Available in PDF from the [CAP Web site](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on July 31, 2013. The information was verified by the guideline developer on August 30, 2013.

## Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

## Disclaimer

### NGC Disclaimer

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Readers with questions regarding guideline content are directed to contact the guideline developer.